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TECH CENTER 1600/2900 PATENT
Customer No. 22,852
Attorney Docket No. 05394-0013

#7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Stewart COLE et al.) Group Art Unit: Not yet assigned
Application No.: 09/936,523) Examiner: Not yet assigned
Filed: September 14, 2001)
For: DELETED SEQUENCES IN M.)
BOVIS BCG/M.BOVIS OR M.)
TUBERCULOSIS, METHOD FOR)
DETECTING MYCOBACTERIA)
USING THESE SEQUENCES AND)
VACCINES)

Commissioner for Patents and Trademarks
Washington, DC 20231

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicant brings to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed documents, including any copending patent applications, are attached.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

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The following is a concise statement of the relevance of the non-English language European patent application 0 461 045 A1, derived from its abstract:

The patent application claims nucleic acid fragments derived from the genome of *Mycobacterium tuberculosis* having the sequences (I), (II), (III) and (IV). (I) has one of the following sequences:

- A : 5'-CCCGCGGCAAAGCCCGCAGGACCACGAYCG-3'
- B : 5'-CGACCCGCCAGCCCAGGATCCTGCGACGT-3'
- C : 5'-GGCGGGTCCAGATGGCTTGCTCGATCGCGT-3'
- D : 5'-GTTGGCGGGTCCAGATGGCTTGCTCGATCG-3'
- E : 5'-TCAAAGGGTTGACAAATTAAATGATTGGTC-3'
- F : 5'-TCGTGTACAAAATGTGGACAAGTA-3'
- G : 5'-TCGACGGACGTGCGTACCGAGAAGTC-3'
- H: 5'-GTCGACACGCCTCTGCACGGGAAGTCCTT-3'

(II) which contains at least 10 of the bases in the sequences A-H, is some 20-40 bases long. (III) which is 20-40 bases long, hybridizes to (I) or (II) and is at least 80% homologous to these sequences. (IV) has a sequence that complements one of (I) (II) or (III). Also claimed is a method for detecting *M. tuberculosis* in a biological sample by contacting it with a probe made up of coupled fragments (primers) chosen from one of the above sequences, followed by amplification, gel electrophoresis and sequencing of the restriction site. Specifically, the probe comprises a sequence up to 20 bases long that can hybridize to a part of the sequence IS6220 situated between two primers. Also claimed is a diagnostic kit and a nucleic acid sequence specific to *M. tuberculosis*.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine

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that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

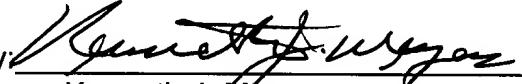
Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: February 12, 2002

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INFORMATION DISCLOSURE CITATION

TECH CENTER 1600/2900

Atty. Docket No.	05394-0013-00000	Serial No.	09/936,523
Applicant	COLE et al.		
Filing Date	September 14, 2001	Group:	Not yet assigned

U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
COPE JC85						
FEB 12 2002						
PATENT & TRADEMARK OFFICE						

FOREIGN PATENT DOCUMENTS

	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	EP 0 461 045 A1	12/11/91	Europe			Abstract
	WO 99/54487	10/28/99	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Mahairas et al., <i>Molecular Analysis of Genetic Differences between Mycobacterium bovis BCG and Virulent M. bovis</i> , J. Bacteriol., Vol. 178, pp. 1274-1282 (1996).
	Harboe, et al., <i>B-Cell Epitopes and Quantification of the ESAT-6 Protein of Mycobacterium tuberculosis</i> , Infection and Immunity, Vol. 66, pp. 717-723 (1998).
	Harboe, et al., <i>Evidence for Occurrence of the ESAT-6 Protein in Mycobacterium tuberculosis and Virulent Mycobacterium bovis and for Its Absence in Mycobacterium bovis BCG</i> , Infection and Immunity, Vol. 64, pp. 16-22 (1996).
	Lagrandieri, et al., <i>Comparison of Immune Responses of Mice Immunized with Five Different Mycobacterium bovis BCG Vaccine Strains</i> , Infection and Immunity, Vol. 64, pp. 1-9 (1996).
	Brosch, et al., <i>Use of a Mycobacterium tuberculosis H37Rv Bacterial Artificial Chromosome Library for Genome Mapping, Sequencing, and Comparative Genomics</i> , Infection and Immunity, Vol. 66, pp. 2221-2228 (1998).
	Philipp, et al., <i>Physical mapping of Mycobacterium bovis BCG Pasteur reveals differences from the genome map of Mycobacterium tuberculosis H37Rv and from M. bovis</i> , Microbiology, Vol. 142, pp. 3135-3145 (1996).
	Harboe, et al., <i>Homology Between the MPB70 and MPB83 Proteins of Mycobacterium bovis BCG</i> , Scand. J. Immuno. Vol. 42, pp. 46-51 (1995).
	Horwitz, et al., <i>Protective immunity against tuberculosis induced by vaccination with major extracellular proteins of Mycobacterium tuberculosis</i> , Proc. Nat'l. Acad. Sci., Vol. 92, pp. 1530-1534 (1995).
	Cole, et al., <i>Deciphering the biology of Mycobacterium tuberculosis from the complete genome sequence</i> , Nature, Vol. 393, pp. 537-544 (1998).

INFORMATION DISCLOSURE CITATION

Atty. Docket No. 05394-0013-00000	Serial No. 09/936,523
Applicant COLE et al.	
Filing Date September 14, 2001	Group: Not yet assigned

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Gordon, et al., <i>Identification of variable regions in the genomes of tubercle bacilli using bacterial artificial chromosome arrays</i> , Mol Microbiol., Vol. 32, pp. 643-55 (1999).
	International Search Report for PCT/FR00/00637, dated July 27, 2000.

Examiner	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

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